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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,292	HOFFMAN ET AL.	
	Examiner	Art Unit	
	KARLHEINZ R. SKOWRONEK	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-52* is/are rejected.

7)☒ Claim(s) *32,34,41 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 32-52 are pending.

Claims 1-31 are cancelled.

Claims 32-52 have been examined.

Claims 32-52 are rejected.

Claims 32, 34, 41, and 49 are objected to.

Priority

This application, filed on 02 January 2004, is a continuation in part of application No. 09/981248 which was filed on 16 October 2001 and claims priority to Provisional application No. 60/509023, filed on 06 October 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12 January 2010 was filed after the mailing date of the first action on the merits on 16 July 2009. The submission complies with the provisions of 37 CFR 1.97(c). Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 32, 34, 41, and 49 are objected to because of the following informalities: Claims 32, 34, 41, and 49 recite the awkward phrase “one family member of the person within the mode of inheritance”, the phrase is being interpreted as “one family member genetically related to the person”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

Response to Arguments

The rejection of claims 41-48 as non-statutory under 35 USC101 is withdrawn in view of the amendment to the claims.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following ground of rejection is reiterated from a previous action.

Claims 32-40 and 49-52 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 32-40 and 49-52 are directed to a process of predicting the likelihood that a person has a mutated form of a gene. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, "Determine Whether the Claimed Invention Complies with 35 USC101". The claims are directed to processes. Here the claims are directed to the abstract idea of predicting the presences of mutated gene. The processes do not recite a physical transformation of matter from one state to another. Giving the claims the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey* (*In re Comiskey*, 84 USPQ2d 1670) the court established that "the application of human intelligence to the solution of practical problems is not and of itself patentable" (at 1680). In *Comiskey*, the court stated explicitly "mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application" (at 1679). The court in *Comiskey* stated, "Following the lead of the

Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed" (at 1680). The court's recent decision in *In re Bilski* confirmed, "a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing" (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. Claims 32-40 and 49-52 recite providing an output or a response to a user. The output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in *Comiskey* stated, "the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that '[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula'" citing *Flook* (437 U.S. at 586, 590). The recent decision in *Bilski* confirmed the court's position regarding insignificant pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 13-96-1397). Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No. 2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Claims 36 and 50 are directed to an embodiment in which the method's instructions are embodied on a computer readable media. At p. 6, paragraph [0022], the specification teaches, "computer readable media may comprise computer storage

media and communication media". [0022] further describes communication media as a carrier wave. As such an embodiment of the claims read on non-statutory subject matter (In re Nuijten 84 USPQ2d 1495 (2007)).

Response to Arguments

Applicant's arguments filed 12 November 2009 have been fully considered but they are not persuasive. Applicant argues claims 32-40 and 49-52 have been amended to recite a tie to a particular machine. The argument is not persuasive. The claim does not recite a significant tie to a particular machine. The amended claims introduce a field of use limitation of a tie to a particular machine by reciting, “A method, implemented by a server, for determining...” The claim should be clear as to how the machine implements the process, rather than simply stating “A method, implemented by a machine,” The machine limitation should make clear that the use of the machine in the claimed process imposes a meaningful limitation on the claims scope.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 32-52 as indefinite under 35 USC 112, Second Paragraph is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 103

Response to Arguments

The rejection of claims 41-48 is withdrawn in view of the amendments to the claims; however, a new ground of rejection over Akers et al., in view of Denton et al., in view of Pathak et al. and in view of Wijker et al. and in view of Lathrop et al.

The rejection of claims 49-52 is withdrawn in view of the amendments to the claims; however, a new ground of rejection over Akers et al., in view of Denton et al., in view of Pathak et al. and in view of Pratt et al. is applied.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claim 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), in view of Pathak et al.

The claims are directed to a method (claims 32-40) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

Akers et al. shows a method and system in which an electronic order for a clinical agent is received (col. 4, line 37-40). Akers et al. shows that the order is automatically checked for adverse reactions (col. 4, line 49-55). Akers et al. shows that a table is searched to identify conflicts with the requested drug. Akers et al. shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

Akers et al. does not show that the conflicts correlate genetic findings associated with the clinical agent or drug.

Denton et al. shows that mutations in genes effects how an individual responds to a clinical agent (p. 3). Denton shows the mutations in a gene can produce atypical events. Denton et al. shows the determination of whether a mutation results in an

atypical event (p. 48) Denton et al. shows the correlation mutations in genes with a person's response to a particular drug in a database, which reads on a table (p. 70). Denton et al. shows the database includes genetic information of the patient and family members (p. 72). Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug (p. 6).

Akers et al. in view of Denton et al. does not show the generation of likelihood that a person has a mutation.

Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2, para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical

decisions (p. 169, col. 2). Regarding claim 34, Pathak et al. teach knowledge sources concerned with allele inheritance relations within the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Regarding claim 35, Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Regarding claim 36, Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Regarding claim 39, Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Regarding claims 33 and 40 Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2)

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial

and error approach to find the optimal drug. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk.

Response to Arguments

Applicant's arguments filed 12 November 2009 have been fully considered but they are not persuasive. Applicant argues the Akers et al. in view of Denton et al. in view of Pathak et al. fails to show the limitation of receiving an order that does not indicate a request to use a genetic test to characterize a patient response to an agent. The argument is not persuasive. Akers et al. shows that the process begins with a selection by a clinician of a patient, a doctor, a drug, and a payment method. The selection of Akers et al. does not include a request for use of a genetic test and thus meet the limitations of the receiving step. Applicant argues that Akers et al. in view of Denton et al. and in view of Pathak et al. fails to show that in response to receiving an order that a table of drug/gene associations is searched. The argument is not persuasive. Akers et al. shows that in response to receiving the order for a clinical agent or drug, a table is automatically searched to identify adverse reactions of the patient or clinical events associated with the drug. Akers et al. does not show that the table of adverse reactions includes gene associations. Denton et al. shows that associating genes and their haplotypes with responses to particular drugs, one can find correlations that predict an individual's response (p. 6-7). Denton et al. shows a result of the drug gene association is that the number of adverse reactions is decreased (p. 5-6).

Together Akers et al. in view of Denton shows the limitation of in response to receiving an order that a table of drug/gene associations is searched. With respect to applicants arguments that Akers et al. in view of Denton et al. in view of Pathak et al. fails to show a step of obtaining the mode of inheritance of the gene, Denton et al. shows that the mode of inheritance is obtained by showing that for any given patient, the haplotypes for the gene is checked for a Mendelian inheritance pattern (p. 16-17). Pathak et al. describes a system that automatically determines genetic risk to establish allele flow or the mode of inheritance from familial data. With respect to the limitation of without solicitation from a clinician querying a second database to determine if a family member has a genetic test result for the gene, Akers et al. shows that upon triggering a request for a drug treatment a conflict table is consulted without solicitation from the clinician, i.e. automatically. Akers et al. shows the table provides data regarding the drug and adverse reaction in the patient. Denton et al. shows that a plurality of databases can be created and correlated using a relational database system (p. 26). Denton et al. shows that among the data collected is familial data. Denton et al. shows in an embodiment in which the response to a treatment may be predicted using the information stored in the databases (p. 9). In figure 29, Denton shows that the pedigree for an individual can be consulted. Pathak et al. shows that pedigree information can by used to automatically determine the genetic risk of an individual from the genetic tests of the family members and predict the likelihood an individual has a mutated form of a gene to the clinician. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of prescribing a treatment for an individual in which a treatment

request for a patient is received and automatically analyzed for potential adverse reactions in the individual before a treatment is administered as in Akers et al. with the haplotype databases and pedigree databases of Denton et al. and the automated determination of genetic risk of Pathak et al. Denton et al. shows that by having unambiguous information about the forms of the protein causing the response to a treatment, one has the ability to predict an individual's response to that treatment accurately (p. 6). Pathak et al. shows that genetic risk influence critical medical decisions and the automated determination of genetic risks streamline the risk computation.

The following new rejection is necessitated by amendment.

Claims 41-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), in view of Pathak et al., in view of Wijker et al. (Hum. Mol. Gen., Vol. 5, No.1, p. 151-154, 1996), and in view of Lathrop et al. (PNAS, Vol. 81, p. 3443-3446, 1984).

The claims are directed to a method (claims 32-40 and 49-52) and system (claims 41-48) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the

probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

Akers et al. shows a method and system in which an electronic order for a clinical agent is received (col. 4, line 37-40). Akers et al. shows that the order is automatically checked for adverse reactions (col. 4, line 49-55). Akers et al. shows that a table is searched to identify conflicts with the requested drug. Akers et al. shows that if a conflict is detected an alert is presented (col. 4, line 58-60).

Akers et al. does not show that the conflicts correlate genetic findings associated with the clinical agent or drug.

Denton et al. shows that mutations in genes effects how an individual responds to a clinical agent (p. 3). Denton shows the mutations in a gene can produce atypical events. Denton et al. shows the determination of whether a mutation results in an atypical event (p. 48) Denton et al. shows the correlation mutations in genes with a person's response to a particular drug in a database, which reads on a table (p. 70). Denton et al. shows the database includes genetic information of the patient and family members (p. 72). Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug (p. 6).

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Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2, para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Regarding claim 43, Pathak et al. teach knowledge sources concerned with allele inheritance relations with in the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Regarding claim 44, Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Regarding claim 48, Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Regarding claims 42 and 45,

Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2).

Akers et al. in view of Denton et al. in view of Pathak et al. do not show searching a table to determine a maximum distance from a gene to find genetic findings of linked genes for the person.

Wijker et al. shows a method in which multilocus linkage analysis is applied to identify location of the gene for PPND to chromosome 17q21 (abstract). Wijker et al. shows a table that is searched to determine the maximum distance from the gene to search for linked genes (table 1). Wijker et al. shows that from the search of the table, markers linked to the gene for PPND are found to exist within a maximum distance of 10 centimorgans (p. 153, col. 1).

Lathrop et al. shows an algorithm for multilocus linkage analysis. Lathrop et al. shows multilocus analysis substantially improves the efficiency of linkage analysis and accuracy of the inferred genetic map (p. 3444, col. 2). Lathrop et al. shows this allows the expression of the disease locus relative to selected test markers (3445, col. 1). Lathrop et al. suggests creating a database of markers (p. 3446, col. 2). Lathrop et al.

shows that multilocus analysis has the further advantage of increased precision of the estimated location of the new locus on the genetic map (p. 3445, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious at the time of invention to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk. It would have been further obvious at the time of invention to modify the method and system of Akers et al. in view of Denton et al. in view of Pathak et al. with the table for determining the maximum distance to search for genes or markers linked to the gene of Wijker et al. because the technique of linkage analysis was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying linkage analysis to a method or device for identifying correlations between gene mutations and treatment responses that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

The following new rejection is necessitated by amendment.

Claim 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers et al. (US PAT 6,112,182), in view of Denton et al. (WO 2001/01218), in view of Pathak et al. and in view of Pratt et al. (Am. J. Hum. Genet., Vol. 66, p. 1153-1157, 2000).

The claims are directed to a method (claims 49-52) in which a prescription for a patient is received from a clinician; determining if the prescribed agent or event is correlated with a gene; querying a database to determine if the patient has genetic results consistent with the correlated gene; if the genetic test results do not exist, obtain the route of inheritance for the gene; query a database to identify any family members with genetic test results with the route of inheritance; use the genetic results of the identified family members to calculate the probability that the patient has a gene mutation; report the probability that the patient has a gene mutation.

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Akers et al. in view of Denton et al. does not show the generation of likelihood that a person has a mutation.

Pathak et al. shows that the likelihood or probability that a person has a mutation in a gene can be determined automatically (p. 164, col. 1). The system analyzes the data and produces a probability of the presence of a mutation. The input of case data as depicted in fig. 1 conceptually demonstrates data that is stored and utilized by the system, thereby reading on the limitation of a database. Consistent with the limitation of a database is the blackboard (p.165, col. 2, para. 1), a global data structure. Pathak et al. teach the input as a set of objects each having the attributes name, sex, parents, siblings, spouse, children, loci (p.165, col. 2, para. 1). The attribute *loci*, as Pathak et al. teach, is a set of alleles in the genome reading on the limitation of genetic test results (p.165, col. 2, para. 1). Pathak et al. teach the use of rule sets to define queries of the case data to identify the route of inheritance based on familial relationships as well as to utilize the loci information to calculate a probability of an allele's presence (p.165, col. 2,

para. 2 and p. 166, col. 2, #8). Pathak et al. shows genetic risks influence medical decisions (p. 169, col. 2). Pathak et al. teach knowledge sources concerned with allele inheritance relations with in the pedigree, reading on mode of inheritance or genetically related family members (p. 165, col. 2, "allele flow"). Pathak et al. teach calculating the likelihood the individual has a mutated form of the gene using the genetic markers (alleles) of at least one family member (p. 166, col. 2, "possible–explanations" and "Bayesian-analysis"). Pathak et al. teach a computer readable media comprising the instructions for the method (p. 169, col. 2, para 2, "software"). Pathak et al. teach the example of x-linked mode of inheritance (p. 167, col. 1, "X-linked"). Pathak et al. teach that all a user must do is provide the system with the relevant data (p. 169, col. 1, last three lines). It is common for an individual's medical information to exist in electronic form and comprise medical data of related family members. Therefore, the teaching of providing the system with the relevant data is viewed to read on the limitations of electronic records from a comprehensive healthcare database. Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk (p. 169, col. 2)

Akers et al. in view of Denton et al. in view of Pathak et al. do not show calculating an inferred finding from Quantitative Trait Loci (QTL) analysis.

Pratt et al. shows the inference of a mutation at a locus by a combination of pedigree (family member association) analysis and QTL analysis (p. 1155, col. 2). Pratt et al. shows that QTL analysis has the benefit of the relative size of the component gives a measure of the magnitude of the effect of a detected locus (.p. 1153, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Akers et al. managing patient care by identifying conflicts in treatments with the identification of correlations between gene mutations and treatment responses of Denton et al. because Denton et al. shows the benefit of correlating drug response with gene mutations is that the best available drug and/or dose for a patient can be prescribed immediately rather than relying on a trial and error approach to find the optimal drug. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. with the automatic determination of genetic likelihoods of Pathak et al. because Pathak et al. shows the system provides the advantage of streamlining the computation of genetic risk. It would have been further obvious to modify the method and system of Akers et al. in view of Denton et al. and the automatic determination of genetic likelihoods of Pathak et al. with the QTL analysis of Pratt et al. because Pratt et al. shows that QTL analysis has the benefit of the relative size of the component gives a measure of the magnitude of the effect of a detected locus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

3 February 2010